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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	)	
	)	MDL NO. 1789
This document relates to: David E. Tundel v. Merck & Co., Inc. Case No: 1:07-cv-6396-JFK	)	1:06-md-1789 (JFK)

DECLARATION OF WILLIAM J. BEAUSOLEIL

WILLIAM J. BEAUSOLEIL declares as follows:

1. I am an attorney admitted to practice before this Court and a partner at Hughes Hubbard & Reed LLP, attorneys for Defendant Merck & Co., Inc. ("Merck"). I am familiar with the facts set forth herein. I make this declaration based on my own personal knowledge and the business records of the Firm.

2. I make this declaration in support of the Motion of Defendant Merck & Co., Inc. to Dismiss Pursuant to Fed. R. Civ. P. 41(a)(1).

3. A true and correct copy of Plaintiff's Complaint, dated May 22, 2006 is attached hereto as Exhibit 1.

4. A true and correct copy of the Order of Dismissal, dated August 31, 2006 is attached hereto as Exhibit 2.

5. A true and correct copy of Plaintiff's Complaint, dated September 1, 2006 is attached hereto as Exhibit 3.

6. A true and correct copy of the Order of Dismissal, dated September 21, 2006 is attached hereto as Exhibit 4.

7. A true and correct copy of Plaintiff's Complaint, dated July 13, 2007 is attached hereto as Exhibit 5.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

/s/
William J. Beausoleil

Executed this
29th day of August, 2007

EXHIBIT 1

Filed 5-22-2006

IN THE CIRCUIT COURT IN AND FOR
ESCAMBIA COUNTY, FLORIDA, CIVIL DIVISION

COPY

DAVID TUNDELL and
LINDA TUNDELL, his wife,

Plaintiff,

CASE NO.: 2006 CA 933

vs.

MERCK & CO., INC., a/k/a and sometimes d/b/a
MERCK SHARP & DOHME (I.A.) CORP.,
a New Jersey corporation,
TAFFANY SHIPP,TOM KIERNAN,
SARAH PACCHETTI, and
SHANA HOLMAN,

Defendants.

COMPLAINT

Plaintiffs David Tundell and Linda Tundell, by and through their undersigned attorneys, allege the following upon information and belief (including an investigation made by and through Plaintiff's counsel), except those allegations which pertain to Plaintiff, which are based on personal knowledge:

I. BACKGROUND

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' wrongful conduct in connection with the manufacturing, distribution, labeling, and selling the prescription drug Fosamax (alendronate).

II. JURISDICTION AND VENUE

2. This Court has jurisdiction over this matter as the injuries complained of occurred in Escambia County, Florida. Plaintiffs are husband and wife and are residents of the State of Florida, County of Escambia. Defendant is incorporated and has its primary place of business in the State of New Jersey. The amount in controversy exceeds $250,000.00.

3. Venue is proper within this Court as a substantial number of events, actions or omissions giving rise to the Plaintiff's claims occurred in this County. At all times relevant to this matter, Defendant Merck conducted substantial business in this County.

III. PARTIES

4. Plaintiff David Tundell was born May 28, 1948. At all relevant times Plaintiff was a resident of Pace, FL, and used FOSAMAX from 2005 until March 2006. David Tundell was married to Linda Tundell at all times material to this action.

5. Defendant, Merck, is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. The Defendant's registered office is at 820 Bear Tavern Road, City of West Trenton, Mercer County, New Jersey.

6. At all times relevant hereto, Merck was engaged in the business of manufacturing, marketing, developing, distributing, promoting, testing, labeling, and/or selling Fosamax throughout the United States and in the State of Florida.

7. Defendant has regularly transacted business in the State of Florida and continues to do so.

8. At all relevant times Defendant, through its agents, servents, employees and apparent agents was the designer, manufacturer, marketer, distributor and seller of Fosamax, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis.

9. Defendant, either directly or through its agents, apparent agents, servants or employees, at all relevant times, sold and distributed Fosamax in the State of Florida for the treatment of osteoporosis, ostepenia, Paget's Disease, and other off-label uses.

10. Defendant TAFFANY SHIPP is a resident of Escambia County, Florida. At all times material hereto, Defendant Shipp was in the business of marketing, promoting, selling and/or distributing the pharmaceutical drug Fosamax (alendronate) in the state of Florida. Defendant Shipp owed various duties to the Plaintiff, but breached those duties by committing positive tortious actions against the Plaintiff.

11. Defendant TOM KIERNAN is a resident of Escambia County, Florida. At all times material hereto, Defendant Kiernan was in the business of marketing, promoting, selling and/or distributing the pharmaceutical drug Fosamax (alendronate) in the state of Florida. Defendant Kiernan owed various duties to the Plaintiff, but breached those duties by committing positive tortious actions against

the Plaintiff.

12. Defendant SARAH PACCHETTI is a resident of Escambia County, Florida. At all times material hereto, Defendant Pacchetti was in the business of marketing, promoting, selling and/or distributing the pharmaceutical drug Fosamax (alendronate) in the state of Florida. Defendant Pacchetti owed various duties to the Plaintiff, but breached those duties by committing positive tortious actions against the Plaintiff.

13. Defendant SHANA HOLMAN is a resident of Escambia County, Florida. At all times material hereto, Defendant Holman was in the business of marketing, promoting, selling and/or distributing the pharmaceutical drug Fosamax (alendronate) in the state of Florida. Defendant Holman owed various duties to the Plaintiff, but breached those duties by committing positive tortious actions against the Plaintiff.

14. As used herein, Defendants Shipp, Kiernan, Pacchetti, and Holman shall be collectively referred to as "Sales Representative Defendants."

15. These positive tortious acts by the Sales Representative Defendants, were committed in their individual and/or corporate capacity, and include, but are not limited to, the following:

a. Sales Representative Defendants failed to convey adequate warnings to the Plaintiff through the prescribing physicians.

b. Sales Representative Defendants were in the business of marketing,

promoting, selling and/or distributing the unreasonably dangerous pharmaceutical drug Fosamax (alendronate) which has caused harm to the Plaintiff.

c. Sales Representative Defendants negligently distributed, marketed, advertised and/or promoted the dangerous drug Fosamax (alendronate).

d. Sales Representative Defendants made negligent misrepresentations regarding the safety and efficacy of the dangerous drug Fosamax (alendronate).

e. Sales Representative Defendants negligently failed to provide sufficient instructions to the Plaintiff and/or her prescribing physician regarding the use of Fosamax (alendronate).

16. All Defendants derive substantial revenue from pharmaceutical products used or consumed in the State of Florida.

17. All Defendants expected, or should have expected, that their business activities could or would have consequences within the State of Florida.

IV. NATURE OF THE CASE

18. Defendant, either directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold FOSAMAX for the treatment of osteoporosis, osteopenia, Paget's Disease, and other off-label uses.

19. As a result of the defective nature of FOSAMAX, persons who were prescribed and ingested FOSAMAX, including Plaintiff, have suffered and may continue to suffer severe and permanent personal injuries, including osteonecrosis of the jaw.

20. Defendant concealed its knowledge of FOSAMAX's unreasonably dangerous risks from Plaintiff David Tundell, other consumers, and the medical community.

21. Defendant failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX after it began marketing, advertising, distributing, and selling the drug.

22. As a result of Defendant's actions, Plaintiff David Tundell was injured due to his ingestion of FOSAMAX, which has caused and will continue to cause Plaintiffs' various injuries and damages. Plaintiffs accordingly seek compensatory damages.

V. FACTUAL BACKGROUND

23. At all relevant times Defendant was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

24. In September 1995, the United State Food and Drug Administration ("FDA") approved Merck's compound alendronate, which is marketed by Merck as FOSAMAX, for various uses, including the treatment of osteoporosis and Paget's Disesase.

25. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone condition such as osteoporosis and Paget's disease. Other drugs within this class such as Aredia and Zometa are also

used in chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.

26. There are two classes of bisphosphonates: the N-contraining (nitrogenous) and non-N containing (non-nitrogenous). The nitrogenous bisphophonates include the following: pamidronate (Aredia); ibandronate (Bondranat); and alendronate (FOSAMAX). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate, like the others, contains a nitrogen atom, whereas etridonate, clodronate, and tiludronate do not. The PDR for FOSAMAX confirms that the molecule contains a nitrogen atom.

27. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Merck knew or should have know that FOSAMAX, as a nitrogenous bisphosphonate, shared a similar adverse event profiles to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

28. Merck knew and or should have known that bisphosphonates, including FOSAMAX, inhibit endothelial cell function. Similarly, Merck knew or should have known that Bisphosponates also inhibit vascularization of the affected area

and induce ischemic changes specific to patients mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

29. Merck also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turning into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

30. Dentists are now being advised by dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on FOSAMAX.

31. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and typically is not reversible.

32. Shortly after Defendant began selling FOSAMAX, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further study risk of osteonecrosis of the jaw relative to FOSAMAX. Rather than evaluating and verifying the safety of FOSAMAX with respect to osteonecrosis of the jaw, Defendant proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of FOSAMAX through 2018.

33. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

34. Since FOSAMAX was released, the FDA has received a significant number of reports of osteonecrosis of the jaw among users of FOSAMAX.

35. On August 25, 2004, the United States Food & Drug Administration ("FDA") posted its ODS Postmarketing Safety Review on bisphosphonates - - specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (FOSAMAX). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.

36. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate, FOSAMAX.

37. As a result, the FDA recommended and stated that the labeling for FOSAMAX should be amended by Defendant to specifically warn about the risk of osteonecrosis of the jaw. Defendant has refused to accede to the FDA's request and, to this day, still does not warn of the risk of osteonecrosis of the jaw in its FOSAMAX labeling.

38. Rather than warn patients, and despite knowledge known by Defendant about increased risk of osteonecrosis of the jaw on patients using FOSAMAX,

Defendant continues to defend FOSAMAX, mislead physicians and the public, and minimize unfavorable findings.

39. FOSAMAX is one of Defendant's top selling drugs, averaging more than $3 billion a year in sales.

40. Consumers, including Plaintiff David Tundell, who have used FOSAMAX for treatment of osteoporosis, have several alternative safer products available to treat the conditions.

41. Defendant knew of the significant risk of dental and oral complications caused by ingestion of FOSAMAX, but Defendant did not adequately and sufficiently warn consumers, including Plaintiff David Tundell, or the medical community, of such risks.

42. As a direct result, Plaintiff David Tundell was prescribed FOSAMAX and has been permanently and severely injured, having suffered serious consequences from the ingestion of FOSAMAX. Plaintiff David Tundell requires and will in the future require ongoing medical care and treatment.

43. Plaintiff David Tundell has suffered from mental anguish from the knowledge that Plaintiff will have life-long complications as a result of the injuries Plaintiff sustained from the use of FOSAMAX.

44. Plaintiff David Tundell was prescribed and began taking FOSAMAX in 1995 and again in December 2005.

45. Plaintiff used FOSAMAX as prescribed and in a foreseeable manner.

46. As a direct and proximate result of using FOSAMAX, Plaintiff suffered severe osteonecrosis of the jaw.

47. Plaintiff, as a direct and proximate result of using FOSAMAX, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

48. Plaintiff used FOSAMAX which had been provided to him in a condition that was substantially the same as the condition in which it was manufactured and sold.

49. Plaintiff would not have used FOSAMAX had Defendant properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

50. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Defendant's fraudulent concealment.

51. As a result of Defendant's actions, Plaintiff and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

COUNTS

COUNT I: STRICT PRODUCT LIABILITY

DEFECTIVE DESIGN

52. The Plaintiff adopts by reference Paragraphs 1 through 51 above, each inclusive, as though fully set forth, pursuant to Rule 1.130(b), Florida Rules of Civil Procedure.

53. At all times material hereto, Defendant Merck and Sales Rep Defendants, engaged in the business of selling, distributing, supplying, manufacturing, marketing and promoting the drug Fosamax (alendronate), which is defective and unreasonably dangerous to consumers, including the Plaintiff.

54. At all times material hereto, the drug Fosamax (alendronate) was sold, distributed, supplied, manufactured, marketed and/or promoted by Defendant Merck and Sales Rep Defendants, it was expected to reach, and did reach, consumers in the State of Florida, including the Plaintiff, without substantial change in the condition in which it was sold.

55. At all times material hereto, Fosamax (alendronate) was sold, marketed, distributed, supplied, manufactured and/or promoted by the Defendant Merck and Sales Rep Defendants, in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

56. When placed in the stream of commerce, the drug contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks which exceeded the benefits of the drug;

(a) When placed in the stream of commerce, it was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with diabetes;

(b) The drug was insufficiently tested;

(c) The drug caused harmful side effects which outweighed any potential utility;

(d) The drug was not accompanied by adequate instructions and/or warnings to fully apprize the consumers, including the Plaintiff, of the full nature or extent of the risks and side effects associated with their use, thereby rendering Defendant Merck and Sales Rep Defendants liable to the Plaintiff, individually and collectively, pursuant to the Restatement (Second) of Torts, § 402A, as adopted by the Florida Courts.

57. As a direct and legal result of the defective condition of the drug, Plaintiff sustained harm, including permanent and debilitating injuries. These injuries caused extensive pain and suffering and severe emotional distress, and substantially reduced Plaintiff's ability to enjoy life; and caused Plaintiff to expend substantial sums of money for medical, hospital, and related care, all to

Plaintiff's general damage.

58. As a direct and legal result of the defective condition of the drug, Plaintiff was injured in health, strength, and activity and had suffered physical injuries as well as mental anguish. In addition, Plaintiff was rendered sick, sore, lame, and disabled, both internally and externally. All of said injuries caused Plaintiff intense anxiety, distress, fear, pain, suffering, and distress secondary to the physical injury and damages.

59. As a direct and legal result of the defective condition of the drug, Plaintiff was unable to work and therefore sustained economic loss, including loss of earnings, and impairment of earning ability in the future.

60. As a direct and legal result of the defective condition of the drug, Plaintiff required reasonable and necessary health care treatment and services and did incur expenses therefore.

61. Plaintiff David Tundell's spouse, Linda Tundell, sustained a loss of consortium as a result of the injuries and damages sustained by her husband's incidental to the use of FOSAMAX. damages include but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.

WHEREFORE, Plaintiff demands judgment against all Defendants for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT II
STRICT PRODUCT LIABILITY
FAILURE TO WARN

62. The Plaintiff adopts by reference Paragraphs 1 through 51 above, each inclusive, as though fully set forth, pursuant to Rule 1.130(b), Florida Rules of Civil Procedure.

63. Plaintiff adopts and re-alleges paragraphs 1 through 48, which are incorporated by reference as if fully set forth herein.

64. The drug was defective and unreasonably dangerous when it left the possession of the Defendant Merck and Sales Rep Defendants in that it contained warnings insufficient to alert consumers, including the Plaintiff herein, to the dangerous risks and reactions associated with the drug, including, but not limited to, increased risk of cardiovascular events, and other serious and life threatening side affects.

65. The Plaintiff used the drug for its intended purposes.

66. The Plaintiff could not have discovered any defect in the drug through the exercise of care.

67. Defendant Merck, as manufacturers of a prescription device, are held to the level of knowledge of an expert in the field.

68. The warnings that were given by Defendant Merck and Sales Rep Defendants were not accurate, clear, and/or were ambiguous.

69. Defendant Merck and Sales Rep Defendants had a continuing duty to warn the Plaintiff of the dangers associated with the drug.

70. As a direct and legal result of the Defendants Merck's and Sales Rep Defendants' failure to warn, Plaintiff sustained harm, including permanent and debilitating injuries. These injuries caused extensive pain and suffering and severe emotional distress, and substantially reduced Plaintiff's ability to enjoy life; and caused Plaintiff to expend substantial sums of money for medical, hospital, and related care during Plaintiff's life, all to Plaintiff's general damage.

71. As a direct and legal result of the Defendant Merck's and Sales Rep Defendants' failure to warn, Plaintiff was injured in health, strength, and activity and had suffered physical injuries as well as mental anguish. In addition, Plaintiff was rendered sick, sore, lame, and disabled, both internally and externally. All of said injuries caused Plaintiff intense anxiety, distress, fear, pain, suffering, and distress secondary to the physical injury and damages.

72. As a direct and legal result of the Defendant Merck's and Sales Rep Defendants' failure to warn, Plaintiff was unable to work and therefore sustained economic loss, including loss of earnings, and impairment of earning ability in the future.

73. As a direct and legal result of the Defendant Merck's and Sales Rep Defendants' failure to warn, Plaintiff required reasonable and necessary health care treatment and services and did incur expenses therefore.

74. Plaintiff David Tundell's spouse, Linda Tundell, sustained a loss of consortium as a result of the injuries and damages sustained by her husband incidental to the use of FOSAMAX. His damages include but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.

WHEREFORE, Plaintiff demands judgment against Defendant Merck and Sales Rep Defendants for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT III
NEGLIGENCE

75. The Plaintiff adopts by reference Paragraphs 1 through 51 above, each inclusive, as though fully set forth, pursuant to Rule 1.130(b), Florida Rules of Civil Procedure.

76. Defendant Merck and Sales Rep Defendants directly or indirectly, negligently and/or defectively made, created, manufactured, assembled, designed, sterilized, tested, labeled, supplied, packaged, distributed, promoted, marketed, advertised, warned, and/or sold, in the State of Florida, the drug Fosamax (alendronate).

77. At all times material hereto, Defendant Merck and Sales Rep Defendants had a duty to Plaintiff to exercise reasonable care in the design, manufacture, testing, processing, advertising, marketing, testing, labeling, assembling, packaging, distribution, promotion and sale of their respective drug products.

78. Defendant Merck and Sales Rep Defendants breached that duty and were negligent in their actions, misrepresentations, and omissions toward Plaintiff in the following ways:

(a) Failed to include adequate warnings with the drug that would alert consumers and physicians to the potential risks and serious side affects of the drug;

(b) Failed to adequately and properly test the drug before placing the drug on the market;

(c) Failed to conduct sufficient testing on the drug which, if properly performed, would have shown that the drug had serious side effects, including, but not limited to, osteonecrosis of the jaw;

(d) Failed to properly and thoroughly analyze the data resulting from the premarketing tests of Fosamax.

(e) Failed to provide adequate post-marketing warnings or instructions after the they knew or should have known of the significant risks associated with the use of the drug;

(f) Encouraged misuse and overuse while underplaying the side effects to doctors and the public in order to make a profit from sales.

79. Defendant Merck and Sales Rep Defendants knew or should have known that the drug caused unreasonably dangerous risks and serious side effects of which the Plaintiff would not be aware. Defendants nevertheless advertised, marketed, sold

and distributed the drug knowing that there were safer methods for the treatment of osteoporosis.

80. As a direct and legal result of the negligence of Defendant Merck and Sales Rep Defendants, Plaintiff sustained harm, including permanent and debilitating injuries. These injuries caused extensive pain and suffering and severe emotional distress, and substantially reduced Plaintiff's ability to enjoy life; and caused Plaintiff to expend substantial sums of money for medical, hospital, and related care, all to Plaintiff's general damage.

81. As a direct and legal result of the negligence of Defendant Merck and Sales Rep Defendants, Plaintiff was injured in health, strength, and activity and had suffered physical injuries as well as mental anguish. In addition, Plaintiff was rendered sick, sore, lame, and disabled, both internally and externally. All of said injuries caused Plaintiff intense anxiety, distress, fear, pain, suffering, and distress secondary to the physical injury and damages.

82. As a direct and legal result of the negligence of Defendant Merck and Sales Rep Defendants, Plaintiff was unable to work and therefore sustained economic loss, including loss of earnings, and impairment of earning ability in the future.

83. As a direct and legal result of the negligence of Defendant Merck and Sales Rep Defendants, Plaintiff required reasonable and necessary health care treatment and services and did incur expenses therefor.

84. Plaintiff David Tundell's spouse, Linda Tundell, sustained a loss of consortium as a result of the injuries and damages sustained by her husband incidental to the use of FOSAMAX. His damages include but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.

WHEREFORE, Plaintiff demands judgment against Defendant Merck and Sales Rep Defendants for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT IV
FRAUD AND MISREPRESENTATION

85. The Plaintiff adopts by reference Paragraphs 1 through 51 above, each inclusive, as though fully set forth, pursuant to Rule 1.130(b), Florida Rules of Civil Procedure.

86. Defendant Merck and Sales Rep Defendants fraudulently, intentionally and/or negligently misrepresented to the Plaintiff, by and through his prescribing physician, and general public, the safety and effectiveness of the drug and/or fraudulently, intentionally and/or negligently concealed material, adverse information regarding the safety and effectiveness of the drug.

87. Defendant Merck and Sales Rep Defendants misrepresentations were communicated to the prescribing physician with the intent that they reach the Plaintiff.

88. Defendant Merck and Sales Rep Defendants either knew or should have known that the representations were false.

89. Defendant Merck and Sales Rep Defendants made the misrepresentations and/or actively concealed this information with the intention and specific desire that the Plaintiff and the consuming public would rely on such in selecting the drug(s) as treatment for osteoporosis, osteopenia, Paget's Disease and other off-label uses.

90. Defendant Merck and Sales Rep Defendants negligently concealed material, adverse information regarding the safety and effectiveness of its product.

91. Defendant Merck and Sales Rep Defendants made these misrepresentations and actively concealed adverse information at a time when Defendant Merck and Sales Rep Defendants knew, or should have known, that their drug product had defects, dangers, and characteristics that were other than what the Defendant Merck had represented to the FDA and the consuming public, including the Plaintiff herein. Specifically, Defendant Merck and Sales Rep Defendants misrepresented to and/or actively concealed from Plaintiff, the FDA, and the consuming public that:

(a) There had been insufficient studies regarding the safety and efficacy of the drug;

(b) Despite knowing that there had been insufficient or inadequate testing of the drug, Defendant Merck and Sales Rep Defendants marketed, promoted and/or sold the drug as if it were fully and adequately tested;

(c) Failed to advise Plaintiff and others that prior studies, research, reports and/or testing had been conducted linking the use of the drug to serious adverse reactions, including, but not limited to, increased cardiovascular events.

(d) Misrepresented and/or actively concealed the fact that Defendant Merck and Sales Rep Defendants knew, or should have known of reports of increased chance of heart attack and stroke associated with the use of the drug;

(e) Misrepresented and/or actively concealed the fact that Defendant Merck and Sales Rep Defendants knew, or should have known, of the greatly increased risk of cardiovascular events; yet despite this Defendant Merck and Sales Rep Defendants were downplaying the risk of the drug;

(f) The misrepresentations of and/or active concealment by Defendant Merck and Sales Rep Defendants were perpetuated directly and/or indirectly by Defendant Merck and Sales Rep Defendants, and their employees, distributors, agents and/or detail persons.

(g) The misrepresentations of and/or active concealment by Defendant Merck and Sales Rep Defendants constitutes a continuing tort.

92. Through Defendants Merck's product insert(s), Defendant Merck and Sales Rep Defendants continued to misrepresent the potential risks and complications associated with the drug.

93. Defendant Merck and Sales Rep Defendants had a post-sale duty to warn Plaintiff about the potential risks and complications associated with the drug in a timely manner.

94. Defendant Merck and Sales Rep Defendants misrepresented the safety and efficacy of the drug product in its labeling, advertising, product inserts, promotional materials, or other marketing efforts.

95. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendant Merck and Sales Rep Defendants to his detriment.

96. Defendant Merck and Sales Rep Defendants continued to promote alternate uses of Fosamax (alendronate) while ignoring the issues raised about the safety of Fosamax (alendronate). They simply tried to redirect attention away from the shortcomings of the drug, when they should have been willing to address the safety concerns.

97. As a direct and legal result of the misrepresentations of Defendant Merck and Sales Rep Defendants, Plaintiff sustained harm, including permanent and debilitating injuries. These injuries caused extensive pain and suffering and severe emotional distress, and substantially reduced Plaintiff's ability to enjoy life; and caused Plaintiff to expend substantial sums of money for medical, hospital, and related care, all to Plaintiff's general damage.

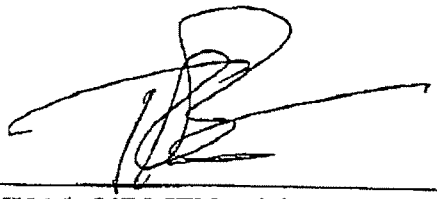
98. As a direct and legal result of the misrepresentations of Defendant Merck and Sales Rep Defendants, Plaintiff was injured in health, strength, and activity and has suffered physical injuries as well as mental anguish. In addition, Plaintiff was rendered sick, sore, lame, and disabled, both internally and externally. All of said injuries caused Plaintiff intense anxiety, distress, fear, pain, suffering, and distress secondary to the physical injury and damages.

99. As a direct and legal result of the misrepresentations of Defendant Merck and Sales Rep Defendants, Plaintiff was unable to work and therefore sustained economic loss, including loss of earnings, and impairment of earning ability in the future.

100. As a direct and legal result of the misrepresentations of Defendant Merck and Sales Rep Defendants, Plaintiff required reasonable and necessary health care treatment and services and did incur expenses therefor.

101. Plaintiff David Tundell's spouse, Linda Tundell, sustained a loss of consortium as a result of the injuries and damages sustained by her husband incidental to the use of FOSAMAX. His damages include but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.

WHEREFORE, Plaintiff demands judgment against Defendant Merck and Sales Rep Defendants for damages, as well as all costs of this action and a trial by jury of all issues to be tried.



TIMOTHY M. O'BRIEN, ESQ.
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(850) 435-7084
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EXHIBIT 2

IN THE CIRCUIT COURT IN AND FOR
ESCAMBIA COUNTY, FLORIDA, CIVIL DIVISION

DAVID TUNDELL and
LINDA TUNDELL, his wife,

Plaintiff,

CASE NO.: 2006 CA 000933

vs.

MERCK & CO., INC., a/k/a and sometimes d/b/a
MERCK SHARP & DOHME (I.A.) CORP.,
a New Jersey corporation,
TAFFANY SHIPP, TOM KIERNAN,
SARAH PACCHETTI, and
SHANA HOLMAN,

Defendants.

NOTICE OF DISMISSAL WITHOUT PREDJUDICE

PLEASE TAKE NOTICE that the Plaintiff, by and through his undersigned attorneys and pursuant to Rule 1.420(a)(1) of the Florida Rules of Civil Procedure, hereby voluntarily dismisses without prejudice the claims against all defendants listed in the caption of this case.

DATED this 31st day of August, 2006.

TIMOTHY M. O'BRIEN, ESQ.
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EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

DAVID TUNDELL

Plaintiff,

Civil Action No.: 3:06cv375/MCR/MD

vs.

MERCK & CO., INC.,

Defendant.

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, David Tundell, through his undersigned attorneys Levin, Papantonio et al., sue Defendant Merck & Company, Inc., and allege as follows:

I. JURISDICTION AND VENUE

1. This Court has jurisdiction pursuant to 28 U.S.C. §§1332, as complete diversity exists between Plaintiff and Defendant. Plaintiff is a resident of the State of Florida, and Defendant is incorporated and has as its primary business in the State of New Jersey. The amount in controversy, exclusive of interest and costs, exceeds $75,000.

R# 300 113556
$ 350.00

2. Venue is proper within this district pursuant to 28 U.S.C. §1391, as a substantial number of the events, actions, or omissions giving rise to the Plaintiffs' claims occurred in this district. At all times relevant to this matter, Defendant Merck conducted substantial business in this district.

II. PARTIES

3. Plaintiff David Tundell was born June 10, 1944. At all relevant times Plaintiff was a resident of Pace, Florida, and used FOSAMAX from 2005 until March 2006.

4. Defendant is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. The Defendant's registered office is at 820 Bear Tavern Road, City of West Trenton, Mercer County, New Jersey.

5. Defendant was at all relevant times authorized to conduct business in the State of Florida.

6. Defendant has regularly transacted business in the State of Florida and continues to do so.

7. At all relevant times Defendant, through its agents, servants, employees and apparent agents was the designer, manufacturer, marketer, distributor and seller of FOSAMAX, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis.

8. Defendant, either directly or through its agents, apparent agents, servants or employees, at all relevant times, sold and distributed FOSAMAX in the State of Florida for the treatment of pain and inflammation.

9. Defendant derives substantial revenue from pharmaceutical products used or consumed in the State of Florida.

10. Defendant expected, or should have expected, that its business activities could or would have consequences within the State of Florida.

III. SUMMARY OF THE CASE

11. Defendant, either directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold FOSAMAX for the treatment of osteoporosis, Paget's Disease, and other off-label uses.

12. As a result of the defective nature of FOSAMAX, persons who were prescribed and ingested FOSAMAX, including Plaintiff David Tundell, have suffered and may continue to suffer severe and permanent personal injuries to the jaw bone, including osteonecrosis of the jaw and other diagnoses of irreversible damage to the jaw.

13. Defendant concealed its knowledge of FOSAMAX's unreasonably dangerous risks from Plaintiff David Tundell, other consumers, and the medical community.

14. Defendant failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX after it began marketing, advertising, distributing, and selling the drug.

15. As a result of Defendant's actions and inaction, Plaintiff David Tundell was injured due to his ingestion of FOSAMAX, which has caused and will continue to cause Plaintiffs' various injuries and damages. Plaintiffs accordingly seek compensatory damages.

IV. FACTUAL BACKGROUND

16. At all relevant times Defendant was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

17. In September 1995, the United States Food and Drug Administration ("FDA") approved Merck's compound alendronate, which is marketed by Merck as FOSAMAX, for various uses, including the treatment of osteoporosis and Paget's Disease.

18. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class such as Aredia and Zometa are also used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.

19. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphophonates include the following: pamidronate (Aredia); ibandronate (Bondronat); and alendronate (FOSAMAX). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate

(Skelid). Alendronate, like the others, contains a nitrogen atom, whereas etridonate, clodronate, and tiludronate do not. The PDR for FOSAMAX confirms that the molecule contains a nitrogen atom.

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21. Merck knew and or should have known that bisphosphonates, including FOSAMAX, inhibit endothelial cell function. Similarly, Merck knew or should have known that Bisphosponates also inhibit vascularization of the affected area and induce ischemic changes specific to patients mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

22. Merck also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turning into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

23. Dentists are now being advised by state dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on FOSAMAX.

24. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and is not reversible.

25. Shortly after Defendant began selling FOSAMAX, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further study risk of osteonecrosis of the jaw relative to FOSAMAX. Rather than evaluating and verifying the safety of FOSAMAX with respect to osteonecrosis of the jaw, Defendant proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of FOSAMAX through 2018.

26. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

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29. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate, FOSAMAX.

30. As a result, the FDA recommended and stated that the labeling for FOSAMAX should be amended by Merck to specifically warn about the risk of osteonecrosis of the jaw. Merck has refused to accede to the FDA's request and, to this day, still does not warn of the risk of osteonecrosis of the jaw in its FOSAMAX labeling.

31. Rather than warn patients, and despite knowledge known by Defendant about increased risk of osteonecrosis of the jaw on patients using FOSAMAX, Defendant continues to defend FOSAMAX and minimize unfavorable findings.

32. FOSAMAX is one of Defendant's top selling drugs. Averaging more than $3 billion a year in sales.

33. Consumers, including Plaintiff David Tundell, who have used FOSAMAX for treatment of osteoporosis, have several alternative safer products available to treat the conditions.

34. Defendant knew of the significant risk of dental and oral complications caused by ingestion of FOSAMAX, but Defendant did not adequately and sufficiently warn consumers, including Plaintiff David Tundell, or the medical community, of such risks.

35. As a direct result, Plaintiff David Tundell was prescribed FOSAMAX and has been permanently and severely injured, having suffered serious consequences from the ingestion of FOSAMAX. Plaintiff David Tundell requires and will in the future require ongoing medical care and treatment.

36. Plaintiff David Tundell has suffered from mental anguish from the knowledge that Plaintiff will have life-long complications as a result of the injuries Plaintiff sustained from the use of FOSAMAX.

37. Plaintiff David Tundell was prescribed and began taking FOSAMAX in 2005.

38. Plaintiff used FOSAMAX as prescribed and in a foreseeable manner.

39. As a direct and proximate result of using FOSAMAX, Plaintiff suffered severe personal injury to the jaw.

40. Plaintiff, as a direct and proximate result of using FOSAMAX, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

41. Plaintiff used FOSAMAX which had been provided to him in a condition that was substantially the same as the condition in which it was manufactured and sold.

42. Plaintiff would not have used FOSAMAX had Defendant properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

43. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Defendant's fraudulent concealment.

44. As a result of Defendant's actions, Plaintiff and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

COUNTS

COUNT I: NEGLIGENCE

45. Plaintiffs re-allege the above as if fully set forth herein.

46. Defendant owed Plaintiff, David Tundell, and other consumers, a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

47. Defendant failed to exercise due care under the circumstances and therefore breached this duty by:

a. failing to properly and thoroughly test FOSAMAX before releasing the drug to market;

b. failing to properly and throughly analyze the data resulting from the pre-marketing tests of FOSAMAX;

c. failing to conduct sufficient post-market testing and surveillance of FOSAMAX;

d. designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

e. failing to exercise due care when advertising and promoting FOSAMAX; and

f. negligently continuing to manufacture, market, advertise, and distribute FOSAMAX after Defendant knew or should have known of its adverse effects.

48. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff David Tundell sustained significant and permanent injuryof the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

49. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT II: STRICT LIABILITY

50. Plaintiffs re-allege the above.

51. Defendant manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a defective and unreasonably dangerous condition to consumers, including Plaintiff David Tundell.

52. Defendant designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

53. Plaintiff used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.

54. FOSAMAX failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

55. FOSAMAX was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.

56. FOSAMAX was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

57. FOSAMAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiff, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.

58. Although Defendant knew or should have known of the defective nature of FOSAMAX, it continued to design, manufacture, market, and sell FOSAMAX so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendant acted with conscious and deliberate disregard of the foreseeable harm caused by FOSAMAX.

59. Plaintiff could not, through the exercise of reasonable care, have discovered FOSAMAX's defects or perceived the dangers posed by the drug.

60. As a direct and proximate consequence of Defendant's conduct, Plaintiff David Tundell sustained significant and permanent injuryof the jaw. In addition, Plaintiff required and will continue to require healthcare. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct

medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

61. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT III: BREACH OF EXPRESS WARRANTY

62. Plaintiffs re-allege the above.

63. Defendant expressly represented to Plaintiff David Tundell and other consumers and the medical community that FOSAMAX was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

64. FOSAMAX does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

65. At all relevant times FOSAMAX did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

66. Plaintiff David Tundell, other consumers, and the medical community relied upon Defendant's express warranties.

67. As a direct and proximate result of Defendant's actions, Plaintiff David Tundell sustained serious significant and permanent injuryof the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

68. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT IV: BREACH OF IMPLIED WARRANTY

69. Plaintiffs re-allege the above paragraphs.

70. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX.

71. At all relevant times, Defendant knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

72. Defendant was aware that consumers, including Plaintiff David Tundell, would use FOSAMAX for treatment of osteoporosis and for other purposes.

73. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Merck to sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.

74. Defendant breached its implied warranty to consumers, including Plaintiff; FOSAMAX was not of merchantable quality or safe and fit for its intended use.

75. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendant's implied warranty for FOSAMAX.

76. FOSAMAX reached consumers without substantial change in the condition in which it was manufactured and sold by Defendant.

77. As a direct and proximate result of Defendant's action, Plaintiff David Tundell sustained significant and permanent injuryof the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffhas incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

78. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT V: FRAUDULENT MISREPRESENTATION

79. Plaintiffs re-allege the above paragraphs.

80. Defendant made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the treatment of pain and inflammation; and

b. Defendant represented that FOSAMAX was safer than other alternative medications.

81. Defendant knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of FOSAMAX to consumers, including Plaintiff, and the medical community.

82. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

83. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.

84. Plaintiff David Tundell, Plaintiff's doctors, and others relied upon the representations.

85. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

86. As a direct and proximate result, Plaintiff David Tundell sustained significant and permanent injuryof the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

87. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive

damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT VI: FRAUDULENT CONCEALMENT

88. Plaintiffs re-allege the above paragraphs.

89. Defendant fraudulently concealed information with respect to FOSAMAX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and

b. Defendant represented that FOSAMAX was safer than other alternative medications and fraudulently concealed information which demonstrated that FOSAMAX was not safer than alternatives available on the market.

90. Defendant had sole access to material facts concerning the dangers and unreasonable risks of FOSAMAX.

91. The concealment of information by Defendant about the risks of FOSAMAX was intentional, and the representations made by Defendant were known by Defendant to be false.

92. The concealment of information and the misrepresentations about FOSAMAX were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

93. Plaintiff David Tundell, Plaintiff's doctors, and others relied upon the representations and were unaware of the substantial dental and oral risks of FOSAMAX which Defendant concealed from Plaintiff's doctors and Plaintiff.

94. As a direct and proximate result of Defendant's fraudulent concealment and misrepresentation, Plaintiff David Tundell suffered significant and permanent injuryof the jaw and was caused to suffer severe and permanent injuries, including pain and mental and physical anguish and suffering, including a diminished capacity for the enjoyment of life, aggravation of preexisting conditions and activation of latent conditions, and a fear of developing other harmful conditions or problems as a result of the injury. Plaintiff has suffered and will continue to suffer a loss of wages and wage-earning capacity and has incurred expense for medical care and treatment due to the injuries caused by FOSAMAX.

95. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

GLOBAL PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendant, as follows:

a. compensatory damages on each cause of action;

b. punitive damages on each cause of action;

c. reasonable attorneys' fees where recoverable;

d. costs of this action; and

e. such other additional and further relief as the Court may deem necessary, appropriate, and just.

VIII. DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and issues so triable.

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(850) 435-7084 FAX (850) 435-7020
Attorney for Plaintiff

EXHIBIT 4

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

DAVID TUNDELL

VS CASE NO. 3:06cv375/MCR/MD

MERCK & CO., INC.

CLERK'S DISMISSAL

Upon Plaintiffs' "NOTICE OF VOLUNTARY DISMISSAL WITHOUT PREJUDICE" filed herein, and pursuant to Rule 41(a)(1), Federal Rules of Civil Procedure, it is

ORDERED AND ADJUDGED that the foregoing entitled cause be, and the same hereby is, dismissed without prejudice.

William M. McCool, Clerk of Court

September 21, 2006
DATE

/s/ C. Justice
Deputy Clerk

Entered On Docket: _____ By: ____
Rules 58 & 79(a) FRCP or 32(d)(1) & 55 FRCRP
Copies mailed to: _____

Document No.

EXHIBIT 5

07 CV 6396

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

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Plaintiff,

Civil Action No.: _____

vs.

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Defendant.

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2. Venue is proper within this district pursuant to Case Management Order No. 3, filed November 1, 2006, signed by John F. Keenan, allowing Fosamax-related cases to be filed directly in the Southern District of New York.

II. PARTIES

3. Plaintiff David E. Tundel was born June 10, 1944. At all relevant times Plaintiff was a resident of Pace, Florida, and used FOSAMAX from approximately July 2005 until

March 2006.

4. Defendant is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. The Defendant's registered office is at 820 Bear Tavern Road, City of West Trenton, Mercer County, New Jersey.

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35. As a direct result, Plaintiff David E. Tundel was prescribed FOSAMAX and has been permanently and severely injured, having suffered serious consequences from the ingestion of FOSAMAX. Plaintiff David E. Tundel requires and will in the future require ongoing medical care and treatment.

36. Plaintiff David E. Tundel has suffered from mental anguish from the knowledge that Plaintiff will have life-long complications as a result of the injuries Plaintiff sustained from the use of FOSAMAX.

37. Plaintiff David E. Tundel was prescribed and began taking FOSAMAX in July 2005.

38. Plaintiff used FOSAMAX as prescribed and in a foreseeable manner.

39. As a direct and proximate result of using FOSAMAX, Plaintiff suffered severe personal injury to the jaw.

40. Plaintiff, as a direct and proximate result of using FOSAMAX, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

41. Plaintiff used FOSAMAX which had been provided to him in a condition that was substantially the same as the condition in which it was manufactured and sold.

42. Plaintiff would not have used FOSAMAX had Defendant properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

43. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Defendant's fraudulent concealment.

44. As a result of Defendant's actions, Plaintiff and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

V. COUNTS

COUNT I: NEGLIGENCE

45. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

46. Defendant owed Plaintiff, David E. Tundel, and other consumers, a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

47. Defendant failed to exercise due care under the circumstances and therefore breached this duty by:

a. failing to properly and thoroughly test FOSAMAX before releasing the drug to market;

b. failing to properly and throughly analyze the data resulting from the pre-marketing tests of FOSAMAX;

c. failing to conduct sufficient post-market testing and surveillance of FOSAMAX;

d. designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

e. failing to exercise due care when advertising and promoting FOSAMAX; and

f. negligently continuing to manufacture, market, advertise, and distribute FOSAMAX after Defendant knew or should have known of its adverse effects.

48. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff David E. Tundel sustained significant and permanent injury to his jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and

related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

49. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT II: STRICT LIABILITY

50. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

51. Defendant manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a defective and unreasonably dangerous condition to consumers, including Plaintiff David E. Tundel.

52. Defendant designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

53. Plaintiff used FOSAMAX as prescribed and in a manner normally intended,

recommended, promoted, and marketed by Defendant.

54. FOSAMAX failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

55. FOSAMAX was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.

56. FOSAMAX was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

57. FOSAMAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiff, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.

58. Although Defendant knew or should have known of the defective nature of FOSAMAX, it continued to design, manufacture, market, and sell FOSAMAX so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendant acted with conscious and deliberate disregard of the foreseeable harm caused by FOSAMAX.

59. Plaintiff could not, through the exercise of reasonable care, have discovered FOSAMAX's defects or perceived the dangers posed by the drug.

60. As a direct and proximate consequence of Defendant's conduct, Plaintiff David E.

Tundel sustained significant and permanent injury to his jaw. In addition, Plaintiff required and will continue to require healthcare as a result of his injury. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

61. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT III: BREACH OF EXPRESS WARRANTY

62. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

63. Defendant expressly represented to Plaintiff David E. Tundel, other consumers and the medical community that FOSAMAX was safe and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

64. FOSAMAX does not conform to Defendant's express representations because it is

not safe, has numerous and serious side effects, and causes severe and permanent injuries.

65. At all relevant times FOSAMAX did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

66. Plaintiff David E. Tundel, other consumers, and the medical community relied upon Defendant's express warranties.

67. As a direct and proximate result of Defendant's actions, Plaintiff David E. Tundel sustained serious significant and permanent injury to his jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of his injury. Plaintiff has incurred and will continue to incur medical and related expenses as a result of his injury. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

68. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT IV: BREACH OF IMPLIED WARRANTY

69. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

70. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX.

71. At all relevant times, Defendant knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

72. Defendant was aware that consumers, including Plaintiff David E. Tundel, would use FOSAMAX for treatment or prevention of osteoporosis or Paget's Disease and for other off-label purposes.

73. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Merck to sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.

74. Defendant breached its implied warranty to consumers, including Plaintiff; FOSAMAX was not of merchantable quality or safe and fit for its intended use.

75. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendant's implied warranty for FOSAMAX.

76. FOSAMAX reached consumers without substantial change in the condition in which it was manufactured and sold by Defendant.

77. As a direct and proximate result of Defendant's action, Plaintiff David E. Tundel sustained significant and permanent injury to his jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of his injury. Plaintiff

has incurred and will continue to incur medical and related expenses as a result of his injury. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

78. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT V: FRAUDULENT MISREPRESENTATION

79. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

80. Defendant made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:

a.. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the treatment of osteoporosis and Paget's Disease; and

b. Defendant represented that FOSAMAX was safer than other alternative

medications.

81. Defendant knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of FOSAMAX to consumers, including Plaintiff, and the medical community.

82. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

83. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.

84. Plaintiff David E. Tundel, Plaintiff's doctors, and others relied upon the representations.

85. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

86. As a direct and proximate result, Plaintiff David E. Tundel sustained significant and permanent injury to his jaw. In addition, as a result of his injury, Plaintiff required and will continue to require healthcare and services, and has incurred and will continue to incur medical and related expenses. Plaintiff also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and

activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

87. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT VI: FRAUDULENT CONCEALMENT

88. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

89. Defendant fraudulently concealed information with respect to FOSAMAX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and

b. Defendant represented that FOSAMAX was safer than other alternative medications and fraudulently concealed information which demonstrated that FOSAMAX was not safer than alternatives available on the market.

90. Defendant had sole access to material facts concerning the dangers and unreasonable risks associated with FOSAMAX.

91. Defendant's concealment of information about the risks associated with taking FOSAMAX was intentional, and the representations made by Defendant were known by Defendant to be false.

92. The concealment of information and the misrepresentations about FOSAMAX were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

93. Plaintiff David E. Tundel, Plaintiff's doctors, and others relied upon the representations and were unaware of the substantial dental and oral risks associated with taking FOSAMAX that Defendant had concealed from them.

94. As a direct and proximate result of Defendant's fraudulent concealment and misrepresentations, Plaintiff David E. Tundel suffered significant and permanent injury to his jaw as well as severe and permanent injuries, including pain, mental and physical anguish and suffering, a diminished capacity for the enjoyment of life, aggravation of preexisting conditions and activation of latent conditions, and a fear of developing other harmful conditions or problems as a result of the injury. Plaintiff has suffered and will continue to suffer a loss of wages and wage-earning capacity and has incurred expenses for medical care and treatment due to the injuries caused by FOSAMAX.

95. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive

damages so as to punish Defendant and deter it from similar conduct in the future.

GLOBAL PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant, as follows:

a. compensatory damages on each cause of action;

b. punitive damages on each cause of action;

c. reasonable attorneys' fees where recoverable;

d. costs of this action; and

e. such other additional and further relief as the Court may deem necessary, appropriate, and just.

VI. DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and issues so triable.

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